DETAILED ACTION

1. This Office Action is in response to Applicant's 15 July 2009 amendment. The Examiner acknowledges Applicant's substitute specification, as well as replacement drawing sheets 1/ 4 and 4/4 and new drawing sheets 2/4 and 3/4, and the amendments to claims 11, 14-19 and 23-26, the addition of claim 30, and the cancellation of claims 12, 13, 20 and 22. Currently, claims 11, 14-19, 21 and 23-30 are pending.

Drawings

2. The drawings are objected to because Figures 1, 1a and 1b present new matter. Specifically, the original specification describes a single catheter with multiple lumens (Figure 3), not multiple catheters as shown in Figures 1 and 1a; the of Figures 1 and 1a were not previously disclosed as being at the distal ends of the lumens; it is unclear whether Applicant intended to show the detection sites as described on page 2 line 28 or page 5 line 20 of the original specification and as such, this appears to be new matter; Applicant's original specification page 2 lines 11-13 describe elements 37 and 38 as if they continue into the body while they do not in Applicant's Figure 1B; and the elements of opposite poles 8 in Figure 1B do not appear to adequately show the opposite poles needed for elements 36, 37 and 38 to work to expand and contract the cage. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The amendment filed 15 July 2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "similar to what is shown in Fig. 1A" (page 8) is not supported by the original disclosure as the original disclosure did not have a Figure 1A, and page 5 line 20 of the original specification describes the contracted form of the balloon as having a "substantially cylindrical envelope" while page 2 line 28 of the original specification describes the contracted form of the cage as "the arms lie in close proximity to one another", so it is new matter

to illustrate, or refer to an illustration where arcuate arms as having a substantially cylindrical envelope; and page 9 the "external" closures and the entire new sentence of page 9 describing the external closures are considered new matter as page 4 lines 2-4 of the original specification discloses both exterior and interior valves/closures, so by limiting the invention later to only exterior closures, the Applicant is adding new matter as Applicant did not previously disclose only the use of exterior closures.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 14-16 and 23-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claims 14 and 23, the Examiner notes that the original specification only disclosed uniformly distributed detections sites with regards to the contact embodiment of Applicant's invention. As Applicant's amendment limited claim 11, and thus all dependent claims, to the non-contact embodiment of Applicant's invention, it

appears that the invention as claimed was not in possession of the Applicant at the time the application was filed. Claims 15 and 16 are rejected as depending on claim 14.

Regarding claim 24, the Examiner notes that the original specification only disclosed an orientation means with regards to the contact embodiment of Applicant's invention. As Applicant's amendment limited claim 11, and thus all dependent claims, to the non-contact embodiment of Applicant's invention, it appears that the invention as claimed was not in possession of the Applicant at the time the application was filed.

Regarding claims 25, the Examiner notes that the original specification only disclosed a curved guide member with regards to the contact embodiment of Applicant's invention. As Applicant's amendment limited claim 11, and thus all dependent claims, to the non-contact embodiment of Applicant's invention, it appears that the invention as claimed was not in possession of the Applicant at the time the application was filed.

6. Claims 11, 14-19, 21 and 23-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Regarding claim 11, it is unclear to the Examiner if the triangulation computations to determine the location of electrical activity on the bladder wall would have enabled Applicant's device to locate the electrical activity on the bladder wall if the detection sites were not in contact with the bladder wall, given that the bladder would not be in a uniform shape around the detection sites and the location of the detection sites with

respect to the bladder would not be known. Claims 14-19, 21 and 23-30 are rejected as ultimately depending on claim 11.

Regarding claim 11, the Examiner notes that no structure has been provided that can determine the location of said electrical activity in the wall, as the claimed structure does not provide a processor or other calculation device. As the claimed structure (the detector and a filling lumen with an external closure) are not capable of performing triangulation or other computations, Applicant's claim is not enabled. See also the 35 USC 112 2nd paragraph of this claim below. Claims 14-19, 21 and 23-30 are rejected as ultimately depending on claim 11.

Regarding claim 26, the Examiner notes that Applicant's disclosure describes the "ablation device" as the tool (see page 7 lines 27-29 of the original specification, as well as Figure 2 where element 21 is the ablation device and clearly does not point to the tip of the tool), while element 22 small RF heat source is at the tip of the ablation device. As Applicant defined an ablation device as the tool in the specification and drawings, it is unclear how Applicant has also disclosed that the "ablation device at a tip of said tool" is enabled. See also the 35 USC 112 2nd paragraph rejection of this claim below.

Regarding claim 30, the Examiner notes that page 8 lines 21-22 of Applicant's original specification states "The inflation lumen is necessarily closed at the distal end by the balloon, but the filling lumen 33 is open." If the inflation lumen is closed by the balloon, the inflation lumen cannot also allow the expandable detector/balloon to pass through it without breaking the end of the balloon closing the distal end, and without the

use of two balloons/expandable detectors. As such, this limitation is not enabled by Applicant's specification.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 11, 14-19, 21 and 23-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 11, the Examiner notes that it is unclear if the claimed apparatus "for detecting the location of electrical activity in the wall of a human bladder" and "an array of detection sites adapted to... whereby the location of said electrical activity in the wall can be determined" is claiming simply the intended use of the detector, or if Applicant intended to claim the use of a processor or other device to perform the determination of the location. The Examiner further notes that a limitation including "can be" in not interpreted as having substantial weight, as this appears to either be optional or an intended use. Further, the Examiner notes the 35 USC 112 1st paragraph rejections of this claim above. Claims 14-19, 21 and 23-30 are rejected as ultimately depending on claim 11.

Regarding claim 26, the Examiner notes that Applicant's disclosure describes the "ablation device" as the tool (see page 7 lines 27-29 of the original specification, as well as Figure 2 where element 21 is the ablation device and clearly does not point to the tip of the tool), while element 22 small RF heat source is at the tip of the ablation device. As Applicant defined an ablation device as the tool in the specification and drawings, it

is unclear if Applicant is claiming that the claimed "ablation tool" has an "ablation device" that then has a tip operable to ablate the surface of the bladder wall (such that three elements are claimed, the ablation tool, an ablation device, and the tip of an ablation device); if Applicant intended to claim that the ablation tool has a small RF heat source at the tip of said tool; or if Applicant intended to claim another relationship between the 3 elements claimed (the ablation tool and an "ablation device at the tip of said tool").

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 11, 14, 15, 18, 19, 21, 23 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over United States Patent 5617876 (van Duyl) as evidenced by "Electromyographic Detection of Purinergic Activity in Guinea Pig Detrusor Smooth Muscle" (Ballaro et al.).

Regarding claim 11, Van Duyl discloses an apparatus for detecting the location of electrical activity in the wall of a human bladder (Figures 2, 4, 6C and 6D), comprising: an expandable non-contact detector adapted to be introduced into the bladder via the urethra in a collapsed condition and reversibly expandable when in the bladder (elastic balloon 3 Figure 2, also Column 7 lines 15-20; the Examiner notes that in the case of use during filling cystometry, the detector would not contact the wall when surrounded by liquid (Column 16 lines 6-19); the Examiner further notes that "non-contact" could be considered as not contacting the exterior of the body, see the 35 USC 112 2nd paragraph rejection of claim 11 above; the Examiner also notes that page 4 lines 13-22 of Applicant's specification describes the non-contact detector as smaller than the contact detector, and van Duyl teaches the use of "two or more sizes" of balloons (Column 9 lines 65-67) as well as filling the balloon to different volumes (see, for example, Column 12 lines 19-21)), and having a connector to the exterior

(electrodes 9 with insulated leads 17 Figures 2 and 4, also catheter 1 Figures 2 and 4); the detector comprising an array of detection sites adapted to detect electrical activity in the wall of the bladder when positioned at a distance from the wall of the bladder, whereby the location of said electrical activity can be determined (electrodes 9 Figures 2, 4, 6C and 6D, also Column 8 lines 7-11 and Column 9 lines 30-35, as well the entire document; additionally, the electrodes of van Duyl measure in the range of μVs (Column 7 line 67-Column 8 line 1) and Ballaro et al. teach measuring electrical activity of the bladder wall in μVs (see Ballaro et al. page 378 Results first 5 lines, Figures 6 and 8) which is evidence that the electrodes of van Duyl would be adapted to measure the electrical activity of the bladder wall as both measurements are in μVs; and the output of van Duyl, if processed with Applicant's disclosed calculations, would be capable of determining the location of electrical activity); a filling lumen having a distal end for insertion via the urethra into the bladder, the distal end defining an open end adapted to permit passage of a sterile fluid from the exterior through the open end directly into the bladder for distending the bladder (the catheter required by Column 16 lines 6-19, see also "would require a separate catheter as conventionally used in such a procedure" (Applicant's 15 July 2009 arguments, page 8)); and an external closure for the filling lumen, the closure being effective when closed to maintain the bladder in a distended state, and being effective when released to drain the bladder (Column 16 lines 6-19, in order for the isovolumetric conditions to occur, the filling lumen inherently has a closure to prevent the fluid from leaking out due the pressure of the bladder; van Duyl does not state if this is an external or internal closure; however, given that the fluid in the filling

lumen is going into and out of the body, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use an external closure to provide an easy and sanitary closure that could be reused as it does not contact any fluids).

Regarding claims 14, 15, 18, 19, 21, 23 and 29 Van Duyl as evidenced by Ballaro et al. teach the apparatus according to claim 11 wherein said detection sites are uniformly distributed on a surface of the detector (Figures 6C and 6D); wherein said expandable detector resembles a sphere in the expanded state (Figures 2, 6C and 6D); wherein the expandable detector comprises an inflatable device (elastic balloon 3 Figure 2); wherein said inflatable device includes an inflation lumen for inflating the inflatable device, the inflation lumen having an external closure (catheter 1 Figures 2 and 4; Column 7 lines 45-53, Column 8 lines 41-45, Column 12 lines 19-21, and Column 16 lines 10-19); further comprising multiple lumens (lumen of catheter 1 and liquid supply line 25 Figure 4, as well as catheter/lumen for draining urine Column 14 lines 52-54, also the catheter required by Column 16 lines 6-19); wherein said detection sites are uniformly distributed (Figures 6C and 6D); and wherein the external closure for the filling lumen comprises a valve (the closure required to maintain isovolumetric conditions in the bladder (Column 16 lines 6-19) (see also the 35 USC 103 rejection of claim 11 above) inherently regulates the flow of liquids through a structure (the filling lumen) which makes it, by definition, a valve).

13. Claims 16, 17 and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over van Duyl as evidenced by Ballaro et al. as applied to claims 11, 14, 15, 18, 19, 21, 23 and 29 above, and further in view of United States Patent 5662108 (Budd et al.).

Regarding claims 16, 17 and 24-28 van Duyl as evidenced by Ballaro et al. disclose the claimed invention, except for the expandable detector comprising a cage having a plurality of arcuate arms extending between opposite poles; an external telescopic connector whereby relative telescoping movement causes the expandable detector to expand and contract on demand; orientation means whereby the orientation of the expandable device in the bladder may be determined from outside the bladder; a lumen adapted to receive a stiff curved guide member for steering of the expandable device; an ablation tool adapted for insertion through the urethra and having an ablation device at a tip of said tool operable to ablate the internal surface of the bladder wall; the tip of said tool is detectable by a position sensing apparatus; the tip of said tool is adapted to be electrically active and wherein said apparatus is adapted to detect said activity.

Budd et al. teach an expandable detector comprising a cage (Budd et al. basket catheter 80 Figure 4) having a plurality of arcuate arms (Budd et al. limb 82 Figure 4) extending between opposite poles (Budd et al. proximal and distal ends of central shaft 86 Figure 4); an external telescopic connector whereby relative telescoping movement causes the expandable detector to expand and contract on demand (Budd et al. Column 8 lines 64-67; the device inherently can contract as it is also removable from

the body); orientation means whereby the orientation of an expandable device in the bladder may be determined from outside the bladder (Budd et al. Column 11 line 44 – Column 12 line 7); a lumen adapted to receive a stiff curved guide member for steering of the expandable device (Budd et al. a catheter such as balloon catheter 94 inherently has a lumen; any lumen can receive a stiff curved guide member for steering it and such devices are well known in the art); an ablation tool (Budd et al. therapy catheter 18 Figure 3) adapted for insertion through the urethra and having an ablation device at a tip of said tool operable to ablate (Budd et al. delivery electrode 60 is at the tip of therapy catheter 18 Figure 3 and Column 5 lines 17-18) the internal surface of the bladder wall; the tip of said tool (Budd et al. delivery electrode 60 Figure 16) is detectable by a position sensing apparatus (Budd et al. locator electrode 68 Figure 16); the tip of said tool is adapted to be electrically active (Budd et al. delivery electrode 60 Figure 3) and wherein said apparatus is adapted to detect said activity (Budd et al. Column 4 lines 42-50).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the previously cited elements of Budd et al. with the invention of van Duyl as evidenced by Ballaro et al. as a substitution of equivalents known in the art for providing an array of electrodes inside the body (the cage having a plurality of arcuate arms extending between opposite poles is an equivalent known in the art for a balloon with electrodes, each providing an array of electrodes that can be closed for insertion into the body and opened for use upon entry to the body, see Budd et al. Figures 3 and 4 and MPEP 2144.06 II Substituting Equivalents Known For The

Same Purpose). It further would have been obvious to combine the previously cited elements of Budd et al. with the invention of van Duyl as evidenced by Ballaro et al. to further provide assurance that the electrodes of Figures 2 and 4 of van Duyl as evidenced by Ballaro et al. are facing in the correct direction (Budd et al.'s orientation means would confirm van Duyl's positioning Column 14 lines 45-48); and to provide for treatment of any abnormalities found (the ablation tool of Budd et al., with the tip being detectable by a position sensing apparatus and adapted to be electrically active would provide for treating any abnormalities found by the invention of van Duyl as evidenced by Ballaro et al.).

14. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over van Duyl as evidenced by Ballaro et al. as applied to claims 11, 14, 15, 18, 19, 21, 23 and 29 above, and further in view of United States Patent 6152920 (Thompson et al.).

Regarding claim 25, van Duyl as evidenced by Ballaro et al. disclose a lumen (catheter 1 Figures 2 and 4). Van Duyl as evidenced by Ballaro et al. does not expressly disclose the use of the lumen to receive a stiff curved guide member for steering of the expandable device. Thompson et al. teach the use of a lumen (Column 9 lines 20-21 "guidewire 46 passes through a lumen in the shaft 14") to receive a stiff curved guide member for steering of the expandable device (guidewire 46 Figure 5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the use of a lumen to receive a stiff curved guide member for steering of the expandable device as taught by Thompson et al. with the invention of

van Duyl as evidenced by Ballaro et al. to provide for directing and/or anchoring the invention of van Duyl as evidenced by Ballaro et al. as it is positioned in the bladder (Thompson et al. Column 9 lines 16-28).

15. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over van Duyl as evidenced by Ballaro et al. as applied to claims 11, 14, 15, 18, 19, 21, 23 and 29 above, and further in view of United States Patent 5293869 (Edwards et al.).

Van Duyl as evidenced by Ballaro et al. discloses the apparatus of claim 21, including the use of multiple lumens. Van Duyl as evidenced by Ballaro et al. does not expressly teach that one of the multiple lumens is adapted to receive the expandable detector therethrough. Edwards et al. teach a lumen that is adapted to receive an expandable detector (sheath 68 is adapted/able to receive expandable detector/basket 70 therethrough, see entire document, including Figures 3 and 4 and Column 6 lines 17-68). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use such a lumen adapted to receive the expandable detector therethrough as taught by Edwards et al. in the invention of van Duyl as evidenced by Ballaro et al. to provide for protecting the expandable detector during entry and exit from the body, to protect the body walls from being injured by the detection sites or the distal end of the expandable detector during entry and exit from the body, and to provide for removing the detection device and inserting another detection device or a treatment device through the same lumen.

Response to Arguments

16. Applicant's arguments, see the paragraph bridging pages 7 and 8, filed 15 July 2009, with respect to the 35 USC 112 2nd paragraph rejection of claim 19 have been fully considered and are persuasive. The 35 USC 112 2nd paragraph rejection of claim 19 has been withdrawn.

17. Applicant's arguments filed 15 July 2009 have been fully considered but they are not persuasive.

18. Regarding Applicant's argument that the electrodes of van Duyl are not able to detect the location of electrical activity in the bladder wall, the Examiner notes that Ballaro et al. provide evidence that activity of the bladder wall is in μVs. Van Duyl's electrodes are able to measure voltage in μVs (Column 7 line 67-Column 8 line 1). As such, the electrodes of van Duyl are capable of measuring electrical activity in the bladder wall. Regarding Applicant's argument that the electrodes of van Duyl only measure distance/movement, the Examiner notes that this is not technically correct. The electrodes measure electrical signals; it is the processing of these signals that allows the device of van Duyl to compute distance/movement. Again, given that the bladder electrical activity is measured in μVs, the structure of van Duyl is capable of providing the electrical signals needed to compute the location of electrical activity in the wall of the bladder given the correct processing.

19. Regarding Applicant's argument that van Duyl does not provide a filling lumen as the filling cystometry discussed by van Duyl would require a separate catheter, the Examiner first notes that it is unclear if Applicant is arguing that their apparatus has a

filling lumen that is integral or attached to the detector, which is not claimed. Further, as van Duyl teaches the use of his detector in filling cystometry which "would require a separate catheter as conventionally used in such a procedure" (Applicant's 15 July 2009 arguments, page 8), van Duyl teaches an apparatus comprising a detector and a filling lumen/catheter that is not integral or attached to the detector, but meets the limitations of Applicant's current claims.

20. Regarding Applicant's arguments that the electrodes of van Duyl must be in contact with the bladder wall in order to be operable, the Examiner first notes that in the case of use during filling cystometry, the detector would not contact the wall when surrounded by liquid (Column 16 lines 6-19). Additionally, the Examiner notes that, as discussed above, the electrodes of van Duyl measure voltage, and not movement (movement is a calculation based on the measured voltage). As such, the structure of van Duyl is capable of measuring electrical activity in the wall of the bladder when positioned at a distance from the wall of the bladder.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. United States Patent Publication 2003/0100930 (Cohen et al.) Figure 6 shows EMG measured in μVs and [0231] describes this graph with respect to the detrusor muscle. As such, this art is also evidence that the electrodes of van Duyl are capable of measuring electrical activity in the wall of the bladder.

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LLOYD whose telephone number is (571)272-2951. The examiner can normally be reached on Monday through Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily M Lloyd
Examiner
Art Unit 3736

/EML/

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736